

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75256_S5

CHEMISTRY REVIEW(S)

ANDA 75-256/S-005

NAME AND ADDRESS OF APPLICANT:

Duramed Pharmaceuticals, Inc.
5040 Lester Road
Cincinnati, OH 45213

PURPOSE OF AMENDMENT/SUPPLEMENT

Alternate manufacturing site for active ingredient - Ethinyl
Estradiol

DATE(S) OF SUBMISSION(S)

March 19, 2001

PHARMACOLOGICAL CATEGORY

Oral Contraceptive

TRADE NAME

None used

NONPROPRIETARY NAME

Desogesterel and Ethinyl Estradiol

DOSAGE FORM

Tablets

POTENCY

0.15 mg/0.03 mg

RX OR OTC

Rx

REMARKS AND CONCLUSION

Approved.

RECALLS

N/A

Reviewer

Mujahid L. Shaikh

Date Completed

7-20-01

cc: ANDA # 75-256
Division File
Field Copy

Endorsements:

HFD-625/M. Shaikh/7/23/01

HFD-625/M. Smela/7/24/01

IS/

IS/ 7/25/01

7/25/01

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **ANDA 75256/005**
Stamp: **20-MAR-2001** Regulatory Due:
Applicant: **DURAMED PHARMS**
5040 LESTER RD
CINCINNATI, OH 45213

Priority:
Action Goal:
Brand Name:
Established Name: **DESOGESTREL; ETHINYL**
ESTRADIOL
Generic Name:
Dosage Form: **TAB (TABLET)**
Strength: **0.15/0.03MG**

Org Code: **600**District Goal: **20-AUG-2001**

| | | | | |
|---------------|---------------------|------------------|---------------------|--------------------------|
| FDA Contacts: | M. DILLAHUNT | (HFD-613) | 301-827-5848 | , Project Manager |
| | M. SHAIKH | (HFD-625) | 301-827-5848 | , Review Chemist |
| | M. SMELA JR | (HFD-625) | 301-827-5848 | , Team Leader |

Overall Recommendation:**ACCEPTABLE on 02-APR-2001 by J. D AMBROGIO (HFD-324) 301-827-0062**

Establishment:

DMF No:

AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **29-MAR-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **DRUG SUBSTANCE**
MANUFACTURER

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CORRESPONDENCE



*The Art of Leadership...
The Science of Change*

Duramed Pharmaceuticals, Inc.
5040 Duramed Drive
Cincinnati, Ohio 45213
(513) 731-9900

CHANGES BEING EFFECTED IN 30 DAYS

March 19, 2001

Mr. Gary Buehler
Acting Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA NO. 75-256 REF NO. 500-005
NDA SUPPL FOR SUPPLIER ADDITION/AT

RE: ANDA #75-256 Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg
Subject: Alternate Drug Substance Manufacturing Site

Dear Mr. Buehler:

In accordance with 21 CFR 314.70(c), we supplement ANDA 75-256 Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg to provide for an alternate site of manufacture under the same DMF reference for the active pharmaceutical ingredient ethinyl estradiol.

Duramed submits this supplement in one (1) volume and includes two (2) copies, an archival copy and a review copy.

We certify that a true copy of the supplement as described in 21 CFR 314.94 (d)(5) has been provided to the Food and Drug Administration, Cincinnati, District Office in Cincinnati, Ohio.

Please direct any written communications to me at the above address. If you have any questions or require any additional information, please contact Ms. Annette Arlinghaus at 513 731-9900, by fax at 513 458-6007, or the undersigned at 513 458-7274.

Sincerely,

John R. Rapoza, M.S., R.Ph.
Sr. Vice President, Regulatory Affairs



me
3/29/01